An Integrated Approach to Reducing Failures in Early Phase Drug Development

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In recent decades, drug discovery efforts have benefited immensely from adoption of technologies such as PCR, high throughput screening, combinatorial chemistry, large scale sequencing and bioinformatics. These efforts have produced thousands of druggable targets and hundreds of lead candidates. The industry, however, is faced with unacceptable failure rates as these lead candidates enter clinical development. Drug developers must now adopt new technologies that will help reduce these failure rates. Accelerator Mass Spectrometry (AMS) is a technology platform that can have significant impact in the early stages of drug development. AMS is currently used for low radiation mass balance studies, drug metabolite profiling, and microdosing studies. However, greater adoption of AMS-based studies has been hampered in the US due to (1) non-existence of GLP-compliant AMS facilities, (2) absence of a dedicated clinical trials facility, and (3) dated regulatory requirements for studying radioactive drugs without an investigational new drug application (IND). Accium BioSciences is establishing the first dedicated clinical trials unit with an on-site analytical facility housing an AMS instrument. The company is dedicated to answering the technological, clinical and operational requirements for the industry. We now firmly support efforts to revise regulatory language in 21 CRF 361.1, adopted in 1975, to enable the study of radioactive drugs without an IND application. Further details of our facility as well as our integrated approach to reducing failures in early phase drug development will be presented.